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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,548	07/16/2003	Robert Flower	14398	5957

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EXAMINER

JOHNSON III, HENRY M

ART UNIT PAPER NUMBER

3739

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/619,548	FLOWER, ROBERT	
	<b>Examiner</b>	<b>Art Unit</b>	
	Henry M. Johnson, III	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 August 2005.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2 and 4-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 26-30 is/are allowed.
- 6) ☐ Claim(s) 1,2 and 4-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date: _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: _____  | 6) <input type="checkbox"/> Other: _____                                    |

### ***Response to Arguments***

Applicant's arguments filed 19 August 2005 with respect to claims 1-2 and 6-25 have been fully considered and are persuasive. The 35 U.S.C. 102 rejections have been withdrawn. New 35 U.S.C. 103 rejections are cited below.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2 and 4-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,443,976 to Flower et al. in view of U.S. Patent 6,351,663 to Flower et al. Flower et al. '976 teaches a method for treating a lesion, such as a CNV or tumor, in an animal. The methods contemplate treating such a lesion by subjecting the lesion to PDT, and subjecting a blood vessel that carries blood into the lesion to thermal photocoagulation to reduce the flow of blood through that vessel and into the lesion (Col. 2, lines 27-35). A fluorescent dye is used to obtain angiograms of the vasculature of interest to permit accurate targeting, while a radiation-absorbing dye is used in dye-enhanced photocoagulation effect treatment of feeder vessels (Col. 7, lines 1-5). This is the step of locating the feeder vessel. The PDT dyes are disclosed as hematoporphyrins, aminolevulinic acids, porphyrins, merocyanines, porphycenes, porfimer sodium, verteporfin, Photofrin II, PH-10, chlorins, zinc phthalocyanine, purpurins, pheophorbides, monoclonal antibody-dye conjugates of any of the foregoing dyes (abstract). The treatment step of thermal photocoagulation is preferably performed after the application of PDT when reperfusion of the CNV is detected, but the inventive methods are not limited to that

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sequence (Col. 6, lines 22-26). The methods and associated steps may be performed in any logical order (Col. 3, lines 36-37). The photocoagulation radiation-absorbing dyes are disclosed as fluorescein, rose bengal and indocyanine green (Col. 7, lines 31-35). Flower et al. teach a relationship between the type of photodynamic dye, the formulation, mode of administration, and dosage level, adjustment of these parameters to fit the particular combination to ensure delivery of an effective amount of the dye formulation to the targeted tissue is possible. (Col. 5, lines 20-26). This implies delivery over a set period of time based on the parameters. The delivery of dyes via liposomes is disclosed as being well known in the art (Col. 8, lines 11-16), and this is interpreted to include the various properties associated therewith. Flower et al. teach the radiation-absorbing dyes may also fluoresce, permitting the same dye to be used to obtain angiographic images of blood vessels, and treatment of vessels targeted as a result of the angiogram (Col. 7, lines 25-30), thus being used to confirm a target has "filled" with a treatment composition. Flower et al. '976 do not disclose administration of the composition as a rapid bolus. Flower et al. '663 teach the introduction a liquid composition for CNV treatment as boluses comprising a fluorescent dye (Col. 4, line 17) and subsequent radiation. Flower et al. '663 further teach angiogram clarity enhancement by the introduction of a plurality of relatively small, yet highly dye-concentrated, boluses of a fluorescent dye composition into an animal, and subsequently obtaining angiograms as the composition passes through the vasculature of interest. The use of this method provides for a greater degree of fluorescence in the composition, and hence greater resolution in the associated angiogram, as compared to angiograms obtained using a composition having a conventional dye concentration. (Col. 3, line 60 – Col. 4, line 5). A saline flush may be administered flowing the bolus (Col. 4, line 58). It would have been obvious to one having ordinary skill in the art at the time the invention was made to introduce the dye as a bolus as taught by Flower et al. '663 in the method of Flower et

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al. '976 as an alternative equivalent means of introduction. Both Flower et al. '976 and Flower et al. '663 disclose the treatment of CNV using the administration of a dye and subsequent radiation. One skilled in the art would clearly look to other art performing the same or similar treatment.

Regarding claims 22-25, Flower et al. '663 specifically teaches the use of the bolus for enhancing the angiographics at various stages of the treatment of vessels. The angiographics are disclosed for determination of flow direction. Such image analysis would be done based on imaged concentrations and therefore would inherently yield rate of movement of the dye in the treated area.

#### ***Allowable Subject Matter***

Claims 26-30 are allowed.

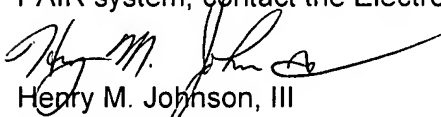
#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Henry M. Johnson, III  
Patent Examiner  
Art Unit 3739